DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 18 2006

Re: Lyrica (NDA 21-723)
Patent No. 6,001,876
Docket No. 2006E-0005

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,001,876, filed by Warner-Lambert Company LLC, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lyrica (NDA 21-723) (pregabalin), the human drug product claimed by the patent.

The total length of the regulatory review period for Lyrica (NDA 21-723) (pregabalin) is 3,279 days. Of this time, 2,852 days occurred during the testing phase and 427 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 10, 1996.

   The applicant claims August 24, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date for pregabalin was January 10, 1996, which was thirty days after FDA receipt of the initial IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: October 31, 2003.

   The applicant claims October 30, 2003, as the date the new drug application (NDA) for Lyrica (NDA 21-723) was initially submitted. However, FDA records indicate that NDA 21-723 was initially submitted on October 31, 2003.

3. The date the application was approved: December 30, 2004.

FDA has verified the applicant's claim that NDA 21-723 was approved on December 30, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Karen DeBenedictis
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